

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Marlene C. SCHWARZ

Group Art Unit: 1762

Appl'n No.: 10/823,636

Examiner: Erma C. Cameron

Filing Date: April 14, 2004

For: METHOD AND APPARATUS FOR
COATING A MEDICAL DEVICE
USING A COATING HEAD

Mail Stop Appeal Brief

COMMISSIONER FOR PATENTS
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APPEAL BRIEF

SIR:

Appellant respectfully submits this brief pursuant to 37 C.F.R. § 41.37. The Commissioner is authorized to charge any applicable fees associated with this filing to deposit account no. 11-0600.

REAL PARTY IN INTEREST

The real party in interest is Boston Scientific Scimed, Inc., assignee of this application. The inventor, Marlene C. Schwarz, executed an assignment to Scimed Life Systems, Inc., which was recorded in the U.S. Patent & Trademark Office (“PTO”) on April 14, 2004, at reel 015225, frame 0505. Effective January 1, 2005, Scimed Life Systems, Inc., changed its name to Boston Scientific Scimed, Inc. Papers documenting that name change were filed on September 25, 2006, with the PTO.

RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known to Appellant, Appellant's legal representative, or the assignee that are related to, will directly affect, will be directly affected by, or will have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

The application was originally filed with 29 claims. In Appellant's response to the February 1, 2006, office action, Appellant canceled claim 29 to expedite allowance. Claims 1-28 remain pending in the present application, have been examined, and stand finally rejected.

Claims 1-28 were rejected under 35 U.S.C. 103(a) on the grounds that the Examiner considers these claims obvious over U.S. Patent No. 6,616,765 to Castro et al. ("Castro"). The Appellant herewith appeals the rejection of all pending claims 1-28 in this filing. These claims are reproduced, in their entirety, in the Appendix.

STATUS OF AMENDMENTS

After receiving a first office action mailed September 28, 2005, Appellant filed an amendment in response. A final rejection issued on February 1, 2006, which did not reject independent claims 1 and 16 over the Castro reference at issue here. Appellant filed a response to the final office action asserting that claims 1-28, without amendment, were patentably distinct over the asserted references. Appellant requested reconsideration of the rejection of claims 1-28, and canceled claim 29 to expedite allowance. The Examiner found the Appellant's response "persuasive" and withdrew the finality of the rejection to claims 1-28 on May 15, 2006.

Appellant filed a response to the May 15, 2006, Office Action asserting that claims 1-28, as previously presented, were patentably distinct over the asserted references. A second final

rejection was mailed on October 24, 2006 (“Final Office Action”), rejecting all claims. Appellant filed a response to the Final Office Action maintaining that claims 1-28, as previously presented without amendment, remained patentably distinct over the asserted Castro reference. However, the Appellant nonetheless amended claims 1 and 27 (which merely incorporated language contained in another limitation of the same claims) to expedite allowance, although Appellant did not acquiesce to the rejection.¹ In response, the Examiner issued an Advisory Action dated February 20, 2007 (“Advisory Action”) that did not enter those amendments, stating that the proposed amendments raise new issues requiring a new search and “appear to be matter.”²

Appellant disagrees that the proposed amendments are new matter or require a new search. Nonetheless, Appellant in this appeal brief respectfully maintains that the claims are patentable without entry of these amendments.³ Thus, the last entered claim amendments were set out in the Appellant’s Response to the September 28, 2005, Office Action, which are incorporated in the claims provided in the Appendix.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to methods for the application of coatings to medical devices, such as the application of therapeutic agents and protective coatings to stents. *See* Published Application No. US 2005/0233061 (hereinafter “PA”), at ¶¶ 10, 13, Abstract. Certain

¹ The Appellant submitted these amendments after final rejection in an effort to accommodate the Examiner in expediting issuance of the claims. The amendments merely incorporated language regarding “gravitational flow” from another limitation in the same claims.

² The Appellant respectfully submits that the Examiner erred in rejecting the proposed amendments, as they do not require a new search or raise new matter. As previously identified by the Appellant, the proposed language was originally used in another limitation in the same amended claims 1 & 27, and thus were the subject of previous searches. In addition, it does not constitute new matter as it was described at least in the specification at p. 12, ¶ 35 and original independent claims 1, 16 and 27.

³ The Appellant filed a pre-appeal brief on February 26, 2007, requesting review of the final rejection of claims 1-28. Over five months later, on August 15, 2007, the Patent Office issued an Office Communication stating that the pre-appeal request was improperly submitted because the request exceeded the page limitation.

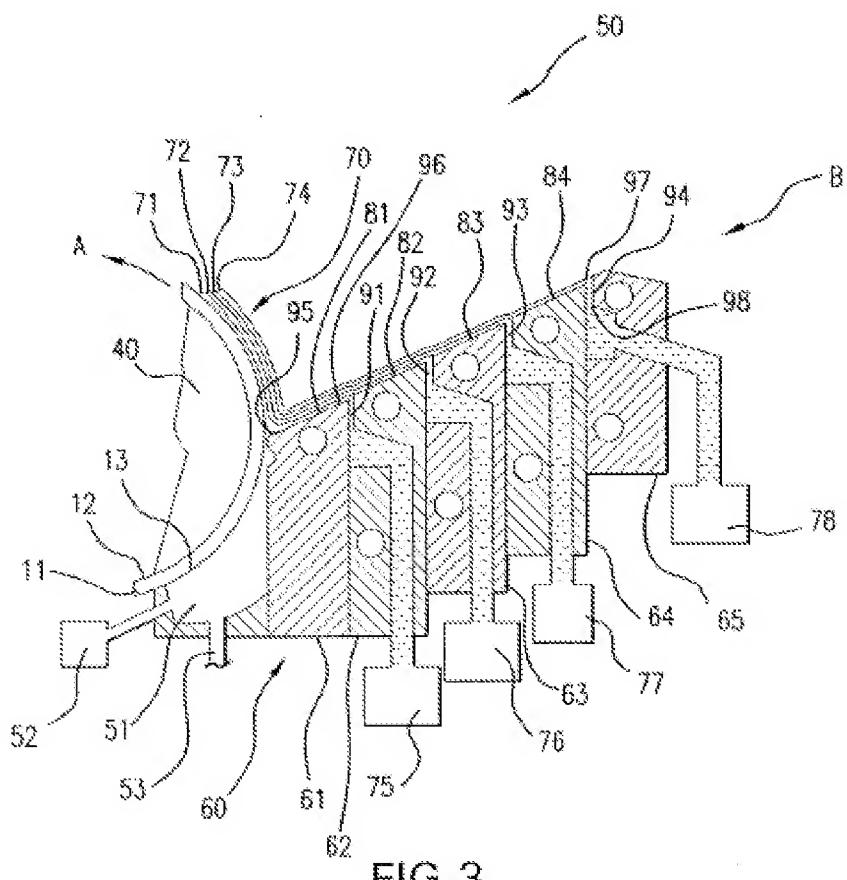
embodiments of the present invention involve a slide coating head “to deposit multiple layers of superposed coating materials. These methods are used to apply one or more coating materials.”

Id., Abstract. Slide coating heads include a slide surface adapted to facilitate gravitational fluid flow on the slide surface, which permits, among other characteristics, the application of highly viscous coating materials, and uniform application of multi-layer coatings without requiring intermediate drying steps. *Id.*, ¶ 17.

Of the 28 claims under appeal, three (claims 1, 16 and 27) are in independent form. Independent claim 1 is directed to a method for coating an implantable medical device with a coating material by providing a slide coating head comprising “a slide surface adapted to facilitate gravitational fluid flow” and an “outlet orifice,” “dispelling the coating material through the outlet orifice onto the slide surface,” and “flowing the coating material down the slide surface” to deposit it onto the medical device. *See, e.g.*, Appellant’s Specification at p. 1, lns. 1-4 [¶11]; p. 10, ln. 4 to p. 11, ln. 3 [¶¶30-31]; p. 11, ln. 8 to p. 12, ln. 17 [¶¶33-35].

Independent claim 16 also is directed to a method for coating an implantable medical device with a slide coating head; however, it discloses a slide coating head with at least two slide surfaces oriented in a manner that allows the second coating material to flow “on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material.” As seen in Figure 3 of the patent application, below, the orientation of inclined slide surfaces 81, 82, 83, 84 permit the formation of a superposed multi-layer coating 70 (of individual coating layers 71, 72, 73, 74) as each individual coating material is dispelled from orifices 91, 92, 93, 94 onto the corresponding slide surfaces. *See, e.g.*, Appellant’s Specification at p. 10, ln. 4 to p. 11, ln. 3 [¶¶30-31]; p. 11, ln. 8 to p. 12, ln. 17 [¶¶33-35]; Fig. 3.

Independent claim 27 is directed to a method for coating a medical device, wherein the medical device is a stent, with a coating material comprising a therapeutic agent by providing a slide coating head comprising “a slide surface adapted to facilitate gravitational fluid flow.” *See, e.g.*, Appellant’s Specification at p. 4, lns. 9-12 [¶13]; p. 6, lns. 17-19 [¶¶22-23]; p. 11, lns. 4-7 [¶32]; p. 15, ln. 4 to p. 16, ln. 9 [¶¶41-42].



GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 1-28 rendered obvious under 35 U.S.C. 103(a) by U.S. Patent No. 6,616,765 to Castro et al. (“Castro”)?

GROUPING OF CLAIMS

As addressed in this appeal, the Appellant is of the view that there are four separate groups of claims that stand or fall independently.

Claims 1-5, 9-15, and 27 constitute one group (“**Group I**”), reciting a method for coating an implantable medical device with a coating material by dispensing the coating material through an outlet orifice onto a slide surface of a slide coating head, and flowing the coating material down the slide surface, which is adapted to facilitate gravitational fluid flow.

Claims 6-8 constitute a second group (“**Group II**”), which depend from independent claim 1, reciting a method for coating an implantable medical device with a coating material by flowing a coating material down a slide surface of a slide coating head, wherein the coating head further comprises a plurality of plates.

Claims 16-23 & 26 constitute a third group (“**Group III**”), reciting a method for coating an implantable medical device with at least two layers of coating material by flowing a first coating material down a first slide surface of a slide coating head and flowing a second coating material down a second slide surface of the coating head, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material on the slide surface.

Claims 24-25 constitute a fourth group (“**Group IV**”), which depend from independent claim 16, reciting a method for coating an implantable medical device with at least two layers of coating material by flowing a first coating material down a first slide surface of a slide coating head and flowing a second coating material down a second slide surface of the coating head, wherein the second slide surface is oriented relative to the first slide surface, and forming a multi-layer coating material, wherein the coating head further comprises a plurality of plates.

ARGUMENT

The pending claims are patentable over the cited Castro reference for several reasons.

First, the Castro patent cannot render obvious claims 1-28 because Castro at least does not disclose or suggest an outlet through which coating is dispelled onto a slide surface. Castro is simply a “syringe” type device with a nozzle “orifice through which [coating material] composition is delivered” generally “by applying a pressure” such as “continuous air pressure” delivered by depressing a plunger or other pressure generating means. *See Castro*, col. 7:37-51; 8:12-22. As seen in Figs. 6A-6C and 7A-7B of Castro, the syringe’s nozzle orifice is positioned over the medical device and the coating material is expelled from the syringe orifice directly onto the medical device. *Id.*, col. 14:56-67, Figs. 6 A-6C and 7A-7B. The rejections cannot stand because Castro does not disclose, and the Examiner has not identified, an outlet orifice on a slide coating head, let alone an outlet orifice through which coating is dispelled onto a slide surface.

Second, the syringe device of Castro cannot render claims 1-28 obvious because Castro does not at least disclose or suggest a “slide surface,” let alone a “slide surface adapted to facilitate gravitational fluid flow on the slide surface.” Rather, Castro describes coating deposition methods characteristic of typical syringe devices (such as the application of pressure) that are independent of gravity and do not require a slide surface as claimed. Castro does not describe any “slide surface adapted to facilitate gravitational fluid flow,” and in fact, teaches away from doing so.

Third, Castro cannot render obvious claims 16-26 because Castro does not at least disclose or suggest orienting a plurality of slide surfaces in any way, let alone disclose or suggest an orientation that allows the formation of a multi-layer coating on a slide surface. Nowhere in Castro is the orientation of a plurality of inner nozzle wall surfaces discussed. To the extent

Castro describes the application of multiple coatings, it discusses directly applying the multiple coatings onto the medical device surface—not the slide surface. The Examiner’s reliance on the doctrine of inherency cannot be applied to reject the claims because there is no evidence that the orientation of slide surfaces must “necessarily flow” from “concurrent” application of multiple coatings. In addition, Castro teaches away from forming multi-layer coatings on slide surfaces.

For at least each of these reasons, and as explained in more detail below, Appellant respectfully asserts that the claims are patentable over Castro.

A. The Claims are Patentable Over Castro Because Castro Does Not Disclose or Suggest an Outlet Orifice Through Which Coating is Dispersed Onto a Slide Surface (Groups I – IV).

United States Patent No. 6,616,765 to Castro et al. (“Castro”) cannot render obvious the rejected claims 1-28 (Groups I through IV) because Castro does not disclose or suggest at least the step of “dispelling the coating material through the outlet orifice onto the slide surface” of the slide coating head, as previously presented in each of independent claims 1, 16 and 27. The Examiner has failed to identify in Castro any “outlet orifice” of a slide coating head, let alone any outlet orifice through which coating material is dispersed “onto the slide surface,” as claimed.

First, the Examiner has yet to identify any particular structure in Castro as the “outlet orifice.” The Examiner initially identified in Castro a “dispensing assembly 22 that includes a nozzle 26 and an orifice 28 (6:16-35).” See May 15, 2006, Office Action, p. 3, ¶6. However, the Appellant pointed out that orifice 28 cannot be the claimed “outlet orifice” because, in Castro, the inner wall of syringe nozzle 26, which the Examiner contends is a slide surface⁴, terminates at orifice 28 for delivery of the coating material. Thus, orifice 28 in Castro, which is merely the

exit of the syringe nozzle, is located downstream of the alleged slide surface, and coating material is dispensed through the orifice 28 as it exits the slide surface. In contrast, the Appellant's claims regard a device that dispels coating material from an upstream orifice onto a slide surface. *See* Appellant's 8/9/06 Response, p. 7.

In response, the Examiner in the Final Office Action changed course and asserted, without particularity, that the outlet orifice can be found somewhere on reservoir 24. *See* Final Office Action, p. 3 ("The examiner would argue that there necessarily must be an opening on reservoir 24 to fill it, in other words, an orifice with which the coating material enters reservoir 24.") But the Examiner already identified this structure in Castro as the claimed "inlet" of the slide coating head. *See* Final Office Action, p. 3 ("Wherever the coating 10 enters the dispenser 22 can be considered an inlet orifice"). Thus, the Examiner evidently considers the "opening on reservoir 24" to constitute both the "inlet" and the "outlet orifice" structures claimed in claims 1, 16 and 27. Accordingly, Castro fails to disclose or suggest at least one of these structures (the inlet or the outlet orifice) of the slide coating head.

Second, whichever structure of Castro the Examiner believes is the "outlet orifice," neither discloses nor suggests "dispelling the coating material through the outlet orifice onto the slide surface." Notwithstanding the Examiner's characterization of the "opening on reservoir 24" as both an inlet and outlet orifice, this opening through "which the coating material enters reservoir 24" does not dispel coating onto a slide surface because the "opening on reservoir 24" is not proximal to the inner wall of syringe nozzle 26, which the Examiner asserts is a slide surface. Rather, the "opening on reservoir 24" allows coating material to enter the intermediary reservoir, which has no "slide surface adapted to facilitate gravitational fluid flow" as claimed.

⁴ The Examiner maintains the inner wall of syringe nozzle 26 is a slide surface, although Appellant disagrees with the characterization. *See* Final Office Action, p. 3 ("Although the '765 does not describe the nozzle as a slide

As seen in Figure 1 of Castro, any “opening on reservoir 24 [through] which the coating material enters reservoir 24” is distal to the inner wall of nozzle 26, and accordingly cannot dispel coating fluid onto the asserted slide surface. Thus, Castro does not at least disclose the step of “dispelling the coating material through the outlet orifice onto the slide surface” of the coating head, as claimed in independent claims 1, 16 and 27.

Third, there is no support, for example, any suggestion or motivation, provided in Castro to modify the syringe-type dispenser of Castro to add the structural feature of an orifice proximal to the conical inner wall of syringe nozzle 26, or the step of dispelling coating through an outlet surface onto a slide surface. Nor does the Examiner point to any.

B. The Claims Are Patentable Over Castro Because Castro Fails To Disclose Or Suggest At Least A Slide Coating Head Comprising “A Slide Surface Adapted To Facilitate Gravitational Fluid Flow On The Slide Surface” (Groups I – IV).

The claims are also patentable over Castro for the independent reason that Castro at least does not disclose or suggest a “slide surface,” let alone a “slide surface adapted to facilitate gravitational fluid flow.” As an initial matter, the syringe device of Castro does not disclose or suggest a “slide surface.” The inner wall of syringe nozzle 26, which the Examiner asserts is a “slide surface,” *see* Final Office Action, p. 3, is simply the inside conical throat surface of a typical syringe nozzle. It is not a “slide surface” as claimed.

Moreover, notwithstanding the Examiner’s contention, the Appellant respectfully asserts that the inner conical syringe nozzle wall of Castro does not disclose or suggest a “slide surface adapted to facilitate gravitational fluid flow on the slide surface,” as claimed in independent claims 1, 16 and 27. Rather, Castro describes using the syringe device with typical coating deposition methods characteristic of syringe devices, and not coating methods that use

coating head, the coating material does slide down the inside of nozzle 26 before reaching the prosthesis 12.”)

gravitational fluid flow to deposit coating onto the surface of the medical device. Castro describes “delivery [of coating material that] can be achieved actively by applying a pressure p to [the coating material] as depicted in Fig. 3A,” or “[d]elivery [that] can be achieved passively via capillary action.” *See Castro, col. 8:12-16.* In other words, Castro describes coating methods that are independent of gravity which utilize non-gravitational capillary action or externally pressurizing the fluid by applying “[c]ontinuous air pressure,” “bursts of air pressure,” or “acoustic, ultrasonic, fluid, or any other forms of pressure,” *see Castro, col. 8:16-22,* thereby allowing the syringe-type device of Castro to overcome the force of gravity.

In addition, there is no support or reason provided in Castro to modify the syringe-type dispenser of Castro to facilitate gravitational fluid flow on the slide surface because Castro teaches away from doing so. Not only does the syringe-type device of Castro describe deposition methods that allow it to overcome gravity as discussed above, but the syringe dispenser assembly 22 of Castro can be rotated (as shown by direction arrow 40 of Fig. 3F) such that the dispenser assembly can be positioned in an upwards direction. *See Castro, col. 8:41-44; Fig. 3F.* Thus, the alleged slide surface of the inner nozzle wall cannot facilitate gravitational fluid flow, thereby necessitating non-gravitational deposition methods.

Furthermore, there can be no support to modify Castro because the proposed modification would change the way Castro operates. *See MPEP 2143.01 (VI)* (no motivation to combine where the “suggested combination would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as a change in the basic principle under which the primary reference’s construction was designed to operate”). Additionally, there can be no support for the proposed change to Castro because modifying the syringe-type device of Castro would render it unusable for its intended purpose of depositing

coating material in a manner that can overcome the forces of gravity. *See MPEP 2143.01 (V)* (“If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”).

Accordingly, Appellant submits that Castro does not disclose at least the limitation of “providing a slide coating head wherein the slide coating head comprises a slide surface adapted to facilitate gravitational fluid flow.”

C. The Claims Are Patentable Over Castro Because Castro Fails To Disclose Or Suggest At Least The Claimed Orientation Of Slide Surfaces Or The Formation Of A Multi-Layer Coating On A Slide Surface (Groups III & IV).

Appellant respectfully asserts that claims 16-26 are allowable for the independent reason that Castro does not disclose or suggest at least the step of “flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material,” as previously presented in independent claim 16. The Final Office Action points to two passages, col. 17:61-68 and col. 18:3-48, in Castro as disclosing the claimed orientation and formation of a multi-layer coating. *See* Final Office Action, p. 3. However, neither passage discloses or suggests a plurality of slide surfaces oriented in such a way to form a multi-layer coating material on a slide surface. In fact, neither passage says anything about the relative orientation or positioning of dispenser assemblies, nor the formation of a unitary, multi-layer coating material on a slide surface, as claimed (as opposed to the formation of a multi-layer coating on a medical device surface).

The first citation (Castro, col. 17:61-68) that the Final Office Action points to reveals nothing about the orientation of a plurality of dispenser assemblies. It merely states that two coating compositions may be deposited concurrently, which the Examiner apparently reads as inherently disclosing both the claimed orientation and the formation of a multi-layer coating on a slide surface. The Appellant respectfully disagrees.

As an initial matter, the cited passage in Castro does not disclose anything about forming a multi-layer coating composition on a slide surface. Rather, it states that the deposition of two separate coating compositions “onto [a] prosthesis” (not a slide surface) can occur concurrently. Concurrent deposition can be achieved by using two dispenser assemblies operating from opposite ends of the prosthesis depositing separate single-layer coatings simultaneously. The cited passage nowhere describes or requires relative orientation of the two dispenser assemblies to form a multi-layer coating material on a slide surface. Accordingly, Castro fails to disclose or suggest at least the orientation of a plurality of dispenser assemblies in any manner, much less suggest or motivate one of skill in the art to orient a plurality of dispenser assemblies in such a way to result in “forming a multi-layer coating material having a layer of second coating material above a layer of first coating material on a slide surface.”

Further, to the extent that the Examiner reads “concurrent” deposition as inherently disclosing both the claimed orientation and formation of a multi-layer coating, the Appellant respectfully asserts that the Examiner has not supplied any “basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the applied art.” M.P.E.P. § 2112, IV (emphasis in original). Appellant respectfully points out that “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described

in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted); *see also Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic.

Here, it has not been shown that the step of “flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material,” would necessarily flow from the cited passage in Castro describing concurrent deposition. Concurrent deposition of two coating materials by two separate dispenser assemblies in Castro does not require relative orientation of the two dispenser assemblies to form a multi-layer coating material on a slide surface. Rather, as discussed above, concurrent deposition involves operation of two dispenser assemblies depositing separate single-layer coatings simultaneously onto a medical device. Accordingly, this step does not necessarily flow from the recited passage in Castro. Moreover, the fact that the “second composition may be deposited concurrently” (*see* Final Office Action, p. 3) is not sufficient to show inherency. Inherency may not be established by probabilities or possibilities. *In re Robertson*, 169 F.3d at 745. Appellant respectfully maintains that the doctrine of inherency cannot supply the missing step. *See* M.P.E.P. § 2112.

The second passage (Castro, col. 18:33-48) that the Final Office Action points to fares no better. It too fails to disclose or suggest a plurality of slide surfaces oriented in such a way to form a multi-layer coating material on a slide surface. In fact, it teaches away from any formation of a multi-layer coating material on a slide surface. Rather, the passage describes depositing a first coating on the medical device surface and then subsequently depositing a second coating on the medical device. For example, the specification states that “[i]n one such embodiment, first composition 10 is deposited on prosthesis 12 as shown in Fig. 14A. Second composition 80 is then deposited to at least partially cover first composition 10 as depicted in Fig. 14B.” See Castro, col. 18:35-39. The remainder of the cited passage similarly recites depositing a first coating and then depositing a second coating. *Id.* col. 18:39-48. Thus, this passage also fails to support Examiner’s contention that Castro discloses or suggests the claimed orientation or the formation of a multi-layer coating on a slide surface.

Accordingly, for at least the reasons stated above, Appellant respectfully submits that claims 16-26 are independently patentable over the Castro reference.

D. The Claims Are Patentable Over Castro Because Castro Fails To Disclose Or Suggest Depositing a Multi-Layer Coating Onto The Surface Of A Medical Device (Groups III & IV).

Castro does not suggest or disclose at least the step of “depositing [a] multi-layer coating material onto the surface of the medical device,” as previously presented in claim 16. Rather, as discussed above, Castro describes depositing a first single-layer coating on a medical device surface, and then depositing a second, subsequent single-layer coating on the medical device, *see* Castro, col. 18:35-48, or depositing the separate single-layer coatings concurrently or simultaneously. *See* Castro, col. 17:61-68. Thus, Castro does not disclose at least the step of “depositing multi-layer coating material onto the surface of the medical device,” and for this independent reason, claims 16-26 are patentably distinct over Castro.

E. The §103 Rejections Of Claims 6-8 And 24-25 Are Improper (Groups II & IV)

Appellant respectfully asserts that dependent claims 6-8 and 24-25 are patentably distinct for the independent reason that Castro does not disclose a plurality of plates. The Final Office Action states that “plate may be defined as any surface within the reservoir 24, and therefore reservoir 24, nozzle 25 [sic, 26], and orifice 26 [sic, 28] may be considered to consist of a plurality of surfaces or plates.”

Foremost, the Examiner has issued an improper § 103 rejection by contending that it is obvious that a reference may disclose a particular feature. A reference either discloses, or fails to disclose, a particular feature. Submitting that the existence of a feature in a reference is obvious is not proper under § 103.

If the Examiner is impliedly taking official notice of a teaching or suggestion of plates, then Appellant respectfully traverses this implied taking and officially requests that the Examiner provide documentary evidence of this teaching or suggestion if this rejection is to be maintained. M.P.E.P. § 2144.03.

Regardless, as depicted throughout the figures of Castro, nozzle 26 is part of a unitary syringe structure 22. Castro does not disclose or suggest a nozzle comprising of separable plates, let alone disclose assembling the plates to form an outlet orifice between the plates, as claimed in claims 7 and 25. Furthermore, there is no support provided in Castro to modify the syringe-type dispenser of Castro to add the structural feature of plates, nor does the Office Action point to any. Accordingly, Appellant respectfully submits that claims 6-8 and 24-25 are independently patentable over the Castro reference for at least this reason as well.

CONCLUSION

For the foregoing reasons, the Appellant respectfully requests favorable consideration by the Board of this appeal and reversal of the final rejection of claims 1-28.

The Office is hereby authorized to charge any applicable fees to Deposit Account No. 11-0600.

Respectfully submitted,

Date: November 1, 2007

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CLAIMS APPENDIX

The claims on appeal read as follows:

1. (Previously Presented) A method for coating at least a portion of an implantable medical device with a coating material comprising:

providing an implantable medical device having a surface;

providing a slide coating head wherein the slide coating head comprises a slide surface adapted to facilitate gravitational fluid flow on the slide surface, and an inlet and an outlet orifice;

flowing a coating material into the inlet;

dispelling the coating material through the outlet orifice onto the slide surface;

flowing the coating material down the slide surface; and

depositing the coating material from the slide surface onto the surface of the medical device.

2. (Previously Presented) The method of claim 1 further comprising translating the medical device relative to the coating head while the coating material is deposited on the surface of the medical device.

3. (Previously Presented) The method of claim 1 further comprising rotating the medical device about a longitudinal axis wherein the coating material is deposited on the surface of the medical device.

4. (Previously Presented) The method of claim 1 further comprising translating the coating head relative to the medical device while the coating material is deposited on the surface of the medical device.
5. (Original) The method of claim 1 further comprising controlling the flow of coating material onto the medical device.
6. (Original) The method of claim 1 wherein the coating head further comprises a first plate and second plate.
7. (Original) The method of claim 6 wherein the first plate and second plate are assembled to form the outlet orifice between the first plate and second plate.
8. (Original) The method of claim 1 wherein the coating head further comprises an upper plate and a lower plate.
9. (Original) The method of claim 1 wherein the medical device is a stent.
10. (Original) The method of claim 1 wherein the coating material comprises a therapeutic agent.
11. (Original) The method of claim 10 wherein the therapeutic agent is selected from the group consisting of pharmaceutically active compounds, proteins, oligonucleotides, DNA compacting agents, recombinant nucleic acids, gene/vector systems, and nucleic acids.

12. (Original) The method of claim 1 wherein the coating material comprises a solvent.
13. (Original) The method of claim 1 wherein the coating material comprises a polymer, sugar, wax, fat or solvent.
14. (Previously Presented) The method of claim 1 wherein the coating head is a curtain coating head.
15. (Original) The method of claim 1 further comprising a holder that holds the medical device for coating.

16. (Previously Presented) A method for coating at least a portion of an implantable medical device with at least two layers of coating material comprising:
- providing an implantable medical device having a surface;
- providing a slide coating head, wherein the slide coating head comprises
- at least a first slide surface and second slide surface, wherein the first slide surface is adjacent the second slide surface and each of the first slide surface and second slide surface is adapted to facilitate gravitational fluid flow on each of the slide surfaces, and
- at least a first inlet and first outlet orifice and second inlet and second outlet orifice;
- flowing a first coating material into the first inlet;
- flowing a second coating material into the second inlet;
- dispelling the first coating material through the first outlet orifice onto the first slide surface;

dispelling the second coating material through the second outlet orifice onto the second slide surface;

flowing the first coating material down the first slide surface;

flowing the second coating material down the second slide surface, wherein the second slide surface is oriented relative to the first slide surface such that the second coating material flows on top of the first coating material on the first slide surface forming a multi-layer coating material having a layer of second coating material above a layer of first coating material; and

depositing the multi-layer coating material onto the surface of the medical device.

17. (Previously Presented) The method of claim 16 further comprising translating the medical device relative to the coating head while the multi-layer coating material is deposited on the surface of the medical device.

18. (Previously Presented) The method of claim 16 further comprising rotating the medical device about a longitudinal axis wherein the multi-layer coating material is deposited on the surface of the medical device.

19. (Previously Presented) The method of claim 16 further comprising translating the coating head relative to the medical device while the multi-layer coating material is deposited on the surface of the medical device.

20. (Original) The method of claim 16 wherein the medical device is a stent.

21. (Original) The method of claim 16 wherein at least one layer of the multi-layer coating material comprises a therapeutic agent.

22. (Original) The method of claim 16 wherein at least one layer of the multi-layer coating material comprises a polymer, sugar, wax, or fat.

23. (Original) The method of claim 16 wherein at least one layer of the multi-layer coating material further comprises a solvent.

24. (Original) The method of claim 16 wherein the slide coating head further comprises a plurality of plates.

25. (Original) The method of claim 24 wherein the plurality of plates are assembled to form a plurality of outlet orifices between the plurality of plates.

26. (Previously Presented) The method of claim 16 wherein the coating head is a curtain coating head.

27. (Previously Presented) A method for coating at least a portion of a medical device with a coating material comprising:

providing a medical device having a surface, wherein the medical device is a stent;

providing a slide coating head wherein the slide coating head comprises a slide surface adapted to facilitate gravitational fluid flow on the slide surface, and at least one inlet and at least one outlet orifice;

flowing a coating material comprising a therapeutic agent into said at least one inlet;
dispelling the coating material through said at least one outlet orifice onto the slide
surface;
flowing the coating material down the slide surface; and
depositing the coating material from the slide surface onto the surface of the medical
device.

28. (Previously Presented) The method of claim 27, wherein the coating head is a curtain
coating head.

29. (Canceled).

EVIDENCE APPENDIX

[NONE]

RELATED PROCEEDINGS APPENDIX

[NONE]